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| ALLERGAN, INC. 2525 DUPONT DRIVE, T2-7H IRVINE, CA 92612-1599 | | | | |
| EXAMINER | | | | |
| HARRIS, ALANA M | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1643 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/071,826

Applicant(s)

BRIN ET AL.

Examiner

Alana M. Harris, Ph.D.

Art Unit

1643

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11 and 34-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11 and 34-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments and Amendments

1. Claims 11 and 34-44 are pending.
Claims 11 and 35 have been amended.
Claims 11 and 34-44 are examined on the merits.

New Grounds of Objection

Specification

2. The disclosure is objected to because of the following informality: it recites the word, "hyperplasic" instead of the proper word, "hyperplastic" for instance on page 1, line 23 and other pages. Applicants are requested to review the entire specification and correction is required.

Claim Objections

3. Claims 35 and 36 are objected to because of the following informality: they recite the word, "hyperplasic" and not "hyperplastic" on the second line of each of the claims. Correction is required.

Withdrawn Rejections

Double Patenting

4. The provisional rejection of claims 11 and 34-44 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 10/929,040 (filed August 27, 2004) is withdrawn in light of Applicants' assertions noted in the Reply, page 5.

5. The provisional rejection of claims 11 and 34-44 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 21-28 and 31 of copending Application No. 11/192,777 (filed December 11, 2007) is withdrawn in light of Applicants' assertions noted in the Reply, page 5.

Maintained Rejection

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The rejection of claims 11 and 34-44 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication 2001/0043930 A1 (effective filing date December 28, 1993), and further in view of Wald and Kakulas (The Australian and New Zealand Journal of Surgery 33(3): 200-204, February 1964) and U.S. Patent number 6,312,708 (filed July 21, 2000) as evidenced by Vakil et al. (C. M. A. Journal 109: 29-32, July 7, 1973) is maintained.

Applicants assert Vakil does not appear to be relevant or related to the claimed invention, as well as none of the cited references alone or in any combination remedy the deficiencies of record in the Reply submitted March 28, 2008, see Reply submitted December 10, 2008, page 3. Applicants reiterate their previous arguments from October 2, 2007 and March 28, 2008 including there is no discussion or hint of botulinum toxin use in Wald and Klaus and no discussion in the patent (further referenced as Donovan). These points of view and Applicants' arguments have been carefully considered, but found unpersuasive.

The Examiner apologizes for not pointing out by page and column where in Vakili it is noted "mammary and certain axillary sweat glands are histologically of the apocrine type and their secretions are biochemically similar", see page 31, 2nd column, 1st paragraph.

The amendment to the claims citing "atypical tissue of the mammary gland" does not preclude the instant rejection. The apocrine gland carcinoma of the breast cited in Wald and Kakulas reference speaks of breast tissue that is not typical or normal. Vakili simply evidenced the tissues of the breast are art known to emit secretions and as indicated by Wald Kakulas. While Wald and Kakulas do not discuss botulinum toxin use that does not teach away from the applicability of using botulinum toxin A in disorders or diseases characterized by releasing mucus secretions as suggested in the publication or Aoki, see abstract; page 1, section 0014; page 2, section 0017; and page 4, Example 5. The publication does not teach treating a mammary gland disorder with administration of the recited dosages in claims 11, 34, 37, 39 and 43 to the mammary gland and the implantation of a botulinum toxin implant.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of all of the documents because Aoki teaches treating various disorders with botulinum toxins and suggests modifications can be made, see page 5, section 0069. Donovan teaches the amount of botulinum A to be injected is generally between about 0.01 units per kilogram to about 35 units per kg, see bridging paragraphs of columns 25 and 26.

One of ordinary skill in the art would have been motivated to treat apocrine gland

carcinoma of the breast with botulinum toxin A using the designated dosages with a reasonable expectation of success by teachings well known in the art, because of the successful treatment of secretions and it is art known that dosages of any composition for treatment must be adjusted and optimized, see Aoki, page 2, sections 0026 and 0027; and page 4, section 0061. Moreover, one of ordinary skill in the art would have motivated to do so with a reasonable expectation of success by teachings in all the references, that medical devices, such as implants are well known in the art for providing controlled or sustained release of pharmaceutical agents to treat disease.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alana M. Harris, Ph.D.
23 February 2009

/Alana M. Harris, Ph.D./
Primary Examiner, Art Unit 1643

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